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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,536	08/25/2003	Robert Owen Lockerbie	B0175-US02	4649

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GAMBRO, INC
PATENT DEPARTMENT
10810 W COLLINS AVE
LAKEWOOD, CO 80215

EXAMINER	
LEE, JAE W	

ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/648,536	LOCKERBIE ET AL.	
	Examiner	Art Unit	
	Jae W. Lee, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-19 and 21-23* is/are pending in the application.

4a) Of the above claim(s) *8 and 11-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,9,10 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application status

In response to the previous Office action, a non-Final rejection (mailed on 02/06/2007), Applicants filed a response and amendment received on 08/06/2007. Said amendment canceled Claim(s) 2, 3 and 20, and amended Claim(s) 1, 5, 10 and 21. Thus, Claim(s) 1, 4-19 and 21-23 is/are at issue and present for examination.

Applicants' arguments filed on 08/06/2007, have been fully considered, and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

It is noted by the Examiner that Claim(s) 8 and 11-19 is/are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention in the previous Office actions, a non-Final rejection (mailed on 02/06/2007).

Claim Objections

The previous objection of Claim 5 is for the recitation of "TPGS" is withdrawn by virtue of Applicant's amendment, wherein Applicants inserted "alpha-tocopheral polyethylene glycol succinate (TPGS)" in claim 5.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The previous rejection of Claims 1-7, 9, 10 and 20-23 under 35 U.S.C. § 112, second paragraph, is withdrawn by virtue of Applicants' amendment, wherein Applicants have deleted the phrase "substantially maintaining damage to pathogen nucleic acid," in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-7, 9, 10 and 21-23 are rejected under 35 U.S.C. § 112, first paragraph, written description, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to previous claims 1-7, 9, 10 and 20-23. In response to this rejection, Applicants have cancelled

claims 2, 3 and 20, amended claims 1, 5, 10 and 21 in the amendment, and traversed the rejection as it applies to the newly amended claims.

Applicants argue that claims as amended recite the phrase "permanent damage," and specify that the photosensitizer is riboflavin and the "light" used is either visible or UV. Therefore, Applicants allege that Applicants comply with the written description requirement under this statute. Further, Applicants point out that "Blood component" is defined on page 1, line 9, "Pathogens" are defined on page 2 line 19, and Example 5 describes the process of damaging the nucleic acids of bacteria (E. coli), Example 5 describes the process of damaging viruses (lambda phage) and Examples 1-3 describes the process of damaging the nucleic acids of undesirable cells (white blood cells).

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. Although the specification on page 1, line 9, states that "[w]hole blood collected from volunteer donors for transfusion into recipients is typically separated into its components: red blood cells, white blood cells, platelets, plasma and plasma proteins," this is not a definition of "blood components." Furthermore, even if such statement clearly defined what "blood components" encompass, limitations from the specification are not read into the claims although the claims are interpreted in light of the specification. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Furthermore, the specification lacks adequate description of the genus of "riboflavin photosensitizers." It is noted by the Examiner that the phrase, "riboflavin

photosensitizer," is not defined in the specification. As such, the genus of "riboflavin photosensitizers" that are used in the claimed methods encompass widely variant species having essentially any structure as long as it comprises a riboflavin moiety. Such a broad genus of "riboflavin photosensitizers" used in the claimed methods are not supported by the disclosure of the instant application. Please refer to the M.P.E.P. section 2163 [R-5] under II, A, 3, (a), (ii) for more details with respect to sufficient number of representative species that should be disclosed to describe a widely variant genus. For the reasons stated herein and in the previous office action, the rejection under this statute is maintained.

Claims 1, 4-7, 9, 10 and 21-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, because the specification, while being enabling for a process comprising steps of: adding to a solution containing platelets, 50 μM of isoalloxazine photosensitizer comprising riboflavin; irradiating a solution containing platelets, 10^6/mL Jurkat cells and 50 μM of isoalloxazine photosensitizer with light, at wavelength of 320 nm and intensity of 7 J/cm^2, to activate isoalloxazine photosensitizer to cause single strand and double strand breaks to the pathogen deoxyribonucleic acids and ribonucleic acids; substantially maintaining (see also the 112 2nd paragraph rejection above) said strand breaks to said pathogen deoxyribonucleic acids and ribonucleic acids; and wherein said strand breaks caused by the isoalloxazine photosensitizer and light, at wavelength of 320 nm and intensity of 7 J/cm^2, is substantially maintained during storage of a solution containing platelets,

10^6/mL Jurkat cells and 50 μM of isoalloxazine photosensitizer after irradiation, further wherein *E. coli* or *E. coli* containing lambda-phage virus was added before the irradiation instead of the Jurkat cells, does not reasonably provide enablement for a process for preventing self-repair of nucleic acid of pathogenic white blood cells, bacteria and/or viruses which may be contained in any blood component comprising the steps of: adding to any blood component a riboflavin photosensitizer; any blood component and riboflavin photosensitizer with light in a visible or UV range at an appropriate wavelength to activate the riboflavin to fragment the nucleic acid of the pathogenic white blood cells, bacteria and/or viruses to cause permanent damage to the nucleic acid; preventing self-repair of the nucleic acid; and wherein the permanent damage to the nucleic acid caused by the photosensitizer and light is maintained over time such that the pathogenic white blood cells, bacteria and/or viruses will not reproduce in any blood component; and a process for providing pathogen reduced fluid containing blood or any blood component suitable for re-infusion into a patient comprising: damaging the nucleic acid of any pathogenic white blood cells, bacteria or viruses which may be present with the blood or any blood component; adding riboflavin to the blood or any blood component; and exposing the blood or any blood component to UV or visible light to activate the riboflavin to fragment the nucleic acid of the pathogenic white blood cells, bacteria or viruses to prevent them from reproducing in the blood or any blood component after re-infusion into the patient. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to previous claims 1-7, 9, 10 and 20-23. In response to this rejection, Applicants have cancelled claims 2, 3 and 20, amended claims 1, 5, 10 and 21 in the amendment, and traversed the rejection as it applies to the newly amended claims.

Applicants argue that claims now specify pathogens as pathogenic white blood cells, bacteria and/or viruses, and photosensitizers as the riboflavin. Also, Applicants point out that claims now reflect the fluid as pathogenic white blood cells, bacteria and/or viruses which may be contained in blood components. Further, Applicants point out that claims now recite the light as either a visible or UV range. Applicants also point out that claims now reflect the nucleic acid damage as those caused by fragmentation of the nucleic acids, and that "the permanent damage to pathogen nucleic acid caused by the photosensitizer and light is maintained over time such that the pathogen will not reproduce."

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. The scope of the claim is not commensurate with the disclosure of the instant application because the claims rejected under this statute, do not place any structural limits on the "riboflavin photosensitizers." The specification does not support the broad scope of the claims which encompass all modifications and fragments of any "riboflavin photosensitizer" that can be used in the claimed methods, especially those modifications and fragments that do not produce reactive oxygen

species (ROS) upon irradiation with light. For the reasons stated herein and in the previous office action, the rejection under this statute is maintained.

Claim Rejections - 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 6, 7, 10, 21 and 23 are rejected under 35 U.S.C. § 102(e) as being anticipated by Goodrich et al. (USPN 6,258,577).

The rejection was stated in the previous office action as it applied to previous claims 1, 3, 6, 7, 10, 20, 21 and 23. In response to this rejection, Applicants have cancelled claims 3 and 20, amended claims 1, 10 and 21, and traverse the rejection as it applies to the newly amended claims.

Applicants argue that the Goodrich reference does not address whether strand breaks in the nucleic acids of pathogens is permanent. Applicants also point to the specification at Figures 1-3b alleging that such disclosure is not taught in the reference of Goodrich.

Applicants' arguments have been fully considered but are not deemed persuasive for the following reasons. The phrase, "to cause permanent damage," is interpreted as an intended use of the photosensitizer which does not affect the active method steps, and would not appear to further limit the method steps of using said peptide. Even assuming that the phrase is a claim limitation, the teachings of Goodrich et al. demonstrate that the use of isoalloxazine or alloxazine photosensitizers causes a "permanent" damage because the damages are propagated to result in the inactivation of the microorganisms such that they will not reproduce.

Further, Applicants argument based on what is taught in the specification of the instant application is irrelevant because limitations from the specification are not read into the claims although the claims are interpreted in light of the specification. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). For the reasons stated herein and in the previous office action, the rejection under this statute is maintained.

Double Patenting

The filing of a terminal disclaimer over claims 1-18 of the Goodrich patent is acknowledged.

Conclusion

Claims 1, 4-7, 9, 10 and 21-23 are rejected for the reasons as stated above. Applicants must respond to the objections/rejections in this Office action to be fully responsive in prosecution.

THIS ACTION IS MADE FINAL.

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patent Examiner: Jae W. Lee, Ph.D.

RICHARD HUTSON, PH.D.
PRIMARY EXAMINER